ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: May 17, 2011

ClinicalTrials.gov ID: NCT00125138

Study Identification

Unique Protocol ID:	13104A
Brief Title:	Melperone (an Anti-Psychotic) in Patients With Psychosis Associated With Parkinson's Disease
Official Title:	Safety and Efficacy of Melperone in the Treatment of Patients With Psychosis Associated With Parkinson's Disease
Secondary IDs:	OV1003 [Former study ID]

Study Status

Record Verification:	May 2011
Overall Status:	Completed
Study Start:	July 2005 []
Primary Completion:	March 2008 [Actual]
Study Completion:	April 2008 [Actual]

Sponsor/Collaborators

Sponsor:	Lundbeck LLC
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 70,130 Serial Number: 0000 Has Expanded Access: No
Human Subjects Review:	Board Status:
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	The purpose of this study is to evaluate the safety and efficacy of three target doses of melperone compared to placebo in the treatment of psychosis associated with Parkinson's disease. Subjects will be enrolled at approximately 20 investigational sites in the United States (U.S.) and 15 Ex-US sites. The maximum study duration will be 10 weeks. Subjects will have the option of continuing in an open-label extension study.
Detailed Description:	Parkinson’s Disease is a progressive neurodegenerative disorder characterized by bradykinesia, rigidity, tremor and abnormal posture and gait. Many patients can have mild to moderate symptoms, while others with advanced disease have symptoms which interfere with activities of daily living to a severe degree. Although effective in addressing motor dysfunction, long-term use of anti-Parkinsonian agents has been implicated as a component in the development of psychiatric side effects including psychosis. Treatment of psychosis with typical antipsychotics is not recommended in this patient population, since even low potency typical antipsychotics can cause marked exacerbations of parkinsonism in Parkinson’s disease patients. The use of atypical antipsychotics (e.g., clozapine, risperidone and quetiapine) has shown some efficacy in the treatment of psychosis in PD patients. Melperone is classified atypical antipsychotic. European experience with melperone spans more than 30 years, and it encompasses an established antipsychotic efficacy profile in the treatment of confusion, anxiety, unrest (particularly in the elderly) and schizophrenia as well as a favorable safety and tolerability profile. Eligible subjects with Parkinson’s disease psychosis will participate in a 1-2 week Screening/Washout Period, a 5 week Titration Phase (one of three doses of melperone or placebo), a 1 week Maintenance Phase and a Taper/Follow-up Period up to 2 weeks. Following the Day 43 assessment, subjects may be given the option of receiving melperone in an open-label extension study.

Conditions

Conditions:	Parkinson's Disease Psychotic Disorders
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	4
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	90 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Melperone HCl - 20 mg	Drug: Melperone HCl 20 mg/day. Strength of melperone syrup is 5 mg/mL
Experimental: Melperone HCl - 40 mg	Drug: Melperone HCl 40 mg/day. Strength of melperone syrup is 5 mg/mL
Experimental: Melperone HCl - 60 mg	Drug: Melperone HCl 60 mg/day. Strength of melperone syrup is 5 mg/mL
Placebo Comparator: Placebo	Drug: Placebo Syrup formulation

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	
Maximum Age:	
Sex:	All
Gender Based:	
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- The subject or subject's legally authorized representative (LAR) must sign and date the IRB/IEC approved Informed Consent Form and HIPAA Authorization (applicable to US sites only) prior to study participation.
- Male or female subjects. If female:
    - Subject is either not of childbearing potential, defined as postmenopausal for at least 1 year or surgically sterile (bilateral tubal ligation, bilateral oophorectomy or hysterectomy), or if of childbearing potential, must comply with a method of birth control acceptable to the investigator during the study, for at least one month prior to randomization and for one month following completion of the study.
    - Subject is not breastfeeding
    - Subjects of childbearing potential must have a negative serum pregnancy test at the screening visit and on Day 1.
- Subjects with a clinical diagnosis of idiopathic Parkinson's Disease, defined as the presence of at least three of the following cardinal features, in the absence of alternative explanations or atypical features:
    - Rest tremor
    - Rigidity
    - Bradykinesia and/or akinesia
    - Postural and gait abnormalities
- Subjects with psychosis:
    - Presence of visual and/or auditory hallucinations, with or without delusions, occurring during the four weeks prior to the screening visit.
    - Symptoms severe enough to clinically warrant treatment with an antipsychotic agent.
    - A Hallucinations or Delusions total item score (frequency x severity) of > 4 on the Neuropsychiatric Inventory (NPI).
        - Subjects currently being treated with an antipsychotic agent who have not had visual and/or auditory hallucinations, with or without delusions, during the four weeks prior to screening, and/or have a Hallucinations or Delusions total item score <4 on the NPI at the screening visit may be washed out (for 7 days or 5 half-lives, whichever is longer) and return for a repeat screening visit. The NPI Hallucinations or Delusions total item score must be ≥4 at the repeat visit to be considered for study entry.
- Subject is on a stable dose of anti-Parkinsonian medication(s) for at least 7 days or 5 half-lives, whichever is longer, prior to the screening visit and is expected to remain on a stable dose for the duration of the study.
- Subject is willing and able to comply with all study procedures.

Exclusion Criteria:

- Subject has any systemic factor contributing to the psychosis such as urinary infection, liver disease, renal failure, anemia, infection or cancer.
- Subject has a history of significant psychotic disorders prior to the diagnosis of Parkinson's Disease, including but not limited to schizophrenia or bipolar disorder.
- Subject has Dementia with Lewy-bodies (DLB).
- Subject has dementia or a major depressive disorder precluding accurate assessment on rating scales.
- Subject has an acute depressive episode at the time of the screening visit.
- A score on the Mini-Mental State Examination (MMSE) of < 21.
- Subject has had a dose adjustment of their antidepressant medication within 30 days prior to the screening visit, or dose adjustments are planned during the duration of the trial.
- Subject has had dose adjustments of an anxiolytic, cognitive enhancer, or other psychotropic medication (excluding antipsychotics) within 30 days prior to screening or dose adjustments are planned during the duration of the trial.

- Subject has received depot antipsychotic agents within the past 3 months.
- Subject has previously failed treatment with clozaril for psychosis in Parkinson's disease. Subjects who discontinued clozaril due to intolerability may be enrolled.
- Subject has used any investigational product within 30 days or 5 half-lives, whichever is longer, prior to screening.
- Subject cannot tolerate a wash-out of antipsychotic medication prior to randomization.
- Subject has a history of a serious respiratory, gastrointestinal, renal, hematologic or other medical disorder.
- Subject has a history of a serious cardiovascular condition (including, but not limited to, Class IV angina or Class IV heart failure) and/or a history of risk factors for Torsade de pointes (Tdp) (including but not limited to current treatment for hypokalemia or family history of long QT syndrome).
- Subject had myocardial infarction within 6 months prior to screening.
- Subject has a screening ECG with corrected QT interval by Bazett's correction formula (QTcB) of greater than 450 msec, if female, or 430 msec, if male.
- Subject requires treatment with an α-agonist agent.
- Subject has uncontrolled seizures, uncontrolled angina, or uncontrolled symptomatic orthostatic hypotension (or orthostatic hypotension leading to a history of falls 3 months prior to screening), or other medical disorders which would make the subject a poor candidate for a clinical trial.
- Subject has a history of severe adverse reactions to antipsychotic medications and/or quinine.
- Subject has clinically significant abnormal laboratory values, ECG, or findings on physical exam.
- Subject has a recent history or current evidence of substance dependence or abuse.
- Subject is unable to ingest liquid medication.
- Subject is currently being treated with Deep Brain Stimulation (DBS).

Randomization Criteria

- Subject has a Hallucinations or Delusions total item score (frequency x severity) of > 4 on the NPI.
- Female subjects of childbearing potential must have a negative serum pregnancy test.
- Subject has remained on a stable dose of anti-Parkinsonian medications.
- Subject has not had a dose adjustment in their antidepressant medication since the screening visit.
- Subjects have been washed out of previous antipsychotic agents for 5 half-lives or 7 days, whichever is longer, after the last dose of medication.
- Subject has not had dose adjustments in an anxiolytic, cognitive enhancer or other psychotropic medication (excluding antipsychotics) since the Screening Visit.

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IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	Subjects were recruited from July 2005 to December 2007. Investigator sites were hospitals, research centers, movement disorder centers, and neurology centers.
Pre-assignment Details	Subjects entered the Screening/Washout Period (for all previous antipsychotic medications) for a maximum of 2 weeks. On Day 1, the criteria for Randomization were reviewed by the investigator and psychiatric, motor function, and safety assessments were performed. Subjects who qualified on Day 1 were randomized to receive melperone or placebo.

Reporting Groups

	Description
Melperone HCl - 20 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 40 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 60 mg	5 mg/mL Melperone syrup orally QHS
Placebo	Syrup with 0.3 mg/mL quinine orally QHS

Overall Study

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
Started	15	20 [1]	25	30
Completed	12	17	21	25
Not Completed	3	3	4	5
Adverse Event	1	0	3	2
Withdrawal by Subject	2	3	1	1
Lack of Efficacy	0	0	0	1
Sponsor decision-pt moved to assist care	0	0	0	1

[1] One subject requested withdrawal prior to treatment; data for the subject are excluded from results.

Baseline Characteristics

Reporting Groups

	Description
Melperone HCl - 20 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 40 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 60 mg	5 mg/mL Melperone syrup orally QHS
Placebo	Syrup with 0.3 mg/mL quinine orally QHS

Baseline Measures

		Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo	Total
Overall Number of Participants		15	19	25	30	89
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	15 participants	19 participants	25 participants	30 participants	89 participants
		68.9 (6.2)	69.0 (11.8)	67.4 (11.2)	68.5 (9.6)	68.4 (10.0)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	15 participants	19 participants	25 participants	30 participants	89 participants
	Female	4 26.67%	6 31.58%	10 40%	10 33.33%	30 33.71%
	Male	11 73.33%	13 68.42%	15 60%	20 66.67%	59 66.29%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Patient Evaluation of Symptoms of Psychosis.
Measure Description	The change in the Scale for Assessment of Positive Symptoms (SAPS) total score. The SAPS total score ranges from 0 to 170, with higher scores indicating more severe psychosis.
Time Frame	6 weeks (from Baseline to end of Maintenance Period)

Analysis Population Description

All randomized subjects who provided informed consent, took at least 1 dose of study drug, and had at least 1 post-baseline efficacy measurement (modified intent-to-treat [MITT] population) were included in the analysis of efficacy.

Reporting Groups

	Description
Melperone HCl - 20 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 40 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 60 mg	5 mg/mL Melperone syrup orally QHS
Placebo	Syrup with 0.3 mg/mL quinine orally QHS

Measured Values

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
Overall Number of Participants Analyzed	12	17	21	25
Patient Evaluation of Symptoms of Psychosis. Least Squares Mean (Standard Error) Unit of measure: Scores on a scale	-9.8 (4.4)	-12.9 (4.0)	-9.7 (3.5)	-10.0 (3.7)

Statistical Analysis 1 for Patient Evaluation of Symptoms of Psychosis.

Statistical Analysis Overview	Comparison Group Selection	Melperone HCl - 20 mg, Placebo
	Comments	The null hypothesis for each endpoint is that each melperone dose has the same mean as placebo; the alternative hypothesis is that at least one dose is more efficacious than placebo. Only subjects with both a baseline and Day 43 (end of Maintenance Phase) value are included.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5177
	Comments	One-sided pairwise p-value comparing each active treatment to placebo.
	Method	ANCOVA
	Comments	One-way ANCOVA: Treatment, country, and baseline anti-psychotic medication status (recent or distant) as factors; baseline measurement as a covariate

Method of Estimation	Estimation Parameter	Other [Difference of LS Mean]
	Estimated Value	0.1
	Confidence Interval	(2-Sided) 95%

		-6.3 to 6.6
	Estimation Comments	[Not specified]

Statistical Analysis 2 for Patient Evaluation of Symptoms of Psychosis.

Statistical Analysis Overview	Comparison Group Selection	Melperone HCl - 40 mg, Placebo
	Comments	The null hypothesis for each endpoint is that each melperone dose has the same mean as placebo; the alternative hypothesis hypothesis is that at least one dose is more efficacious than placebo. Only subjects with both a baseline and Day 43 (end of Maintenance Phase) value are included.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.1519
	Comments	One-sided pairwise p-value comparing each active treatment to placebo.
	Method	ANCOVA
	Comments	One-way ANCOVA: Treatment, country, and baseline anti-psychotic medication status (recent or distant) as factors; baseline measurement as a covariate.

Method of Estimation	Estimation Parameter	Other [Difference of LS mean]
	Estimated Value	-2.9
	Confidence Interval	(2-Sided) 95% -8.5 to 2.7
	Estimation Comments	[Not specified]

Statistical Analysis 3 for Patient Evaluation of Symptoms of Psychosis.

Statistical Analysis Overview	Comparison Group Selection	Melperone HCl - 60 mg, Placebo
	Comments	The null hypothesis for each endpoint is that each melperone dose has the same mean as placebo; the alternative hypothesis is that at least one dose is more efficacious than placebo. Only subjects with both a baseline and Day 43 (end of Maintenance Phase) value are included.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.5406
	Comments	One-sided pairwise p-value comparing each active treatment to placebo.

	Method	ANCOVA
	Comments	One-way ANCOVA: Treatment, country, and baseline anti-psychotic medication status (recent or distant) as factors; baseline measurement as a covariate.

Method of Estimation	Estimation Parameter	Other [Difference of LS mean]
	Estimated Value	0.3
	Confidence Interval	(2-Sided) 95% -5.2 to 5.8
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Investigator/Caregiver Evaluations of Motor Function
Measure Description	The change in the motor section of the Unified Parkinson's Disease Rating Scale (UPDRS III - motor exam) score. Scores on the UPDRS III - motor exam range from 0 to 108, with higher scores indicating more severe motor symptoms.
Time Frame	6 weeks (from Baseline to end of Maintenance Period)

Analysis Population Description

All randomized subjects who provided informed consent, took at least 1 dose of study drug, and had at least 1 post-baseline efficacy measurement (modified intent-to-treat [MITT] population) were included in the analysis of efficacy.

Reporting Groups

	Description
Melperone HCl - 20 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 40 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 60 mg	5 mg/mL Melperone syrup orally QHS
Placebo	Syrup with 0.3 mg/mL quinine orally QHS

Measured Values

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
Overall Number of Participants Analyzed	12	17	21	25

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
Investigator/Caregiver Evaluations of Motor Function Mean (Standard Deviation) Unit of measure: Scores on a scale	0.7 (8.5)	1.8 (12.9)	0.9 (11.1)	0.5 (6.4)

Statistical Analysis 1 for Investigator/Caregiver Evaluations of Motor Function

Statistical Analysis Overview	Comparison Group Selection	Melperone HCl - 20 mg, Melperone HCl - 40 mg, Melperone HCl - 60 mg, Placebo
	Comments	Only subjects with both a baseline and a post-baseline value are included.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9212
	Comments	Overall p-value using a one-way ANCOVA.
	Method	ANCOVA
	Comments	One-way ANCOVA: Treatment, country, and baseline anti-psychotic medication status (recent or distant) as factors; baseline measurement as a covariate.

Reported Adverse Events

Time Frame	AEs were recorded from administration of study drug on Day 1 to 30 days after the last dose of study drug. SAEs were collected from when the informed consent and HIPAA (US sites only) were signed to 30 days after the last dose of study drug.
Adverse Event Reporting Description	All AEs, expected or unexpected, that occurred during the study, whether observed by the investigator or by the subject and whether or not these events were thought to be related to study drug, were reported and followed-up until resolved or until the investigator judged that further follow-up was not necessary.

Reporting Groups

	Description
Melperone HCl - 20 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 40 mg	5 mg/mL Melperone syrup orally QHS
Melperone HCl - 60 mg	5 mg/mL Melperone syrup orally QHS

	Description
Placebo	Syrup with 0.3 mg/mL quinine orally QHS

All-Cause Mortality

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	/	/	/	/

Serious Adverse Events

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	2/15 (13.33%)	2/19 (10.53%)	2/25 (8%)	0/30 (0%)
Cardiac disorders				
Angina pectoris [A] †	0/15 (0%)	1/19 (5.26%)	0/25 (0%)	0/30 (0%)
Infections and infestations				
Viral infection [A] †	0/15 (0%)	1/19 (5.26%)	0/25 (0%)	0/30 (0%)
Investigations				
Muscle strain [A] †	0/15 (0%)	1/19 (5.26%)	0/25 (0%)	0/30 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung neoplasm malignant [A] †	1/15 (6.67%)	0/19 (0%)	0/25 (0%)	0/30 (0%)
Nervous system disorders				
Parkinson's Disease [A] †	1/15 (6.67%)	0/19 (0%)	1/25 (4%)	0/30 (0%)
Syncope vasovagal [A] †	1/15 (6.67%)	0/19 (0%)	0/25 (0%)	0/30 (0%)
Skin and subcutaneous tissue disorders				
Benign prostatic hyperplasia [A] †	0/15 (0%)	0/19 (0%)	1/25 (4%)	0/30 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (10.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Melperone HCl - 20 mg	Melperone HCl - 40 mg	Melperone HCl - 60 mg	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/15 (40%)	8/19 (42.11%)	10/25 (40%)	6/30 (20%)
Infections and infestations				
Urinary tract infection [A] †	2/15 (13.33%)	2/19 (10.53%)	0/25 (0%)	1/30 (3.33%)
Nervous system disorders				
Parkinson's Disease [A] †	2/15 (13.33%)	4/19 (21.05%)	5/25 (20%)	4/30 (13.33%)
Somnolence [A] †	2/15 (13.33%)	3/19 (15.79%)	6/25 (24%)	2/30 (6.67%)

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA (10.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The PI could publish the results of the Study after the earlier of (a) the cooperative publication of the data, or (b) 18 months after Sponsor’s final evaluation of all data; the PI will submit for review and approval any proposed abstracts and manuscripts at least 45 days prior to submission. The Institution and PI agree to delete any information the Sponsor deems confidential or proprietary; if the parties disagree, then they agree to meet prior to submission to discuss and resolve the issues.

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